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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,200

07/15/2005

Toshihiro Ito

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EXAMINER

GEORGE, PATRICIA ANN

ART UNIT

PAPER NUMBER

1781

NOTIFICATION DATE

DELIVERY MODE

05/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/542,200	Applicant(s) ITO ET AL.	
	Examiner Patricia A. George	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misaki in view of the combination of Kwak, Nanbu, and Tamaki (6,436,462).

The reference of WO/2008/140065 is provided as evidence.

Misaki teaches grain compositions, such as rice or barley (column 1, lines. 7-8) are coated with vitamins (column 2, lines. 43-45) and an iron salt (column 9, line 47) that have further been coated with an emulsifying agent (column 9, line 49).

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Misaki also teaches vitamin and mineral enriched rice that has been coated (column 1, lines 54-57) with hydrogenated oil (column 2, lines 56-57) and glycerol fatty acid esters (column 2, line 65).

Misaki teaches rice or barley (column 1, lines 7-8) coated with an iron salt (column 9, line 47), hydrogenated oil (column 2, lines 56-57) and glycerol fatty acid esters (column 2, line 65), as in claim 2.

Misaki does not teach the coating of the iron salt with an emulsifying agent.

Kwak teaches methods of improving the solubility of minerals, such as iron, by encapsulating (i.e. coating) the minerals used in food, so that more of the mineral is usable by the consumer. Kwak further teaches that conventionally the iron has been added to food as a means to increase iron content, however problems arise because of low solubility of the mineral, and therefore means to alleviate this problem are to try to microencapsulate the iron with a water soluble polyglycerin monostearate which is an emulsifying agent and equivalent to a polyglycerol fatty acid ester (col. 3, lines 21-22), as in claims 1 and 3. Therefore Kwak teaches an emulsifier- coated iron salt composition, similar to that claimed, as for use in foods. See reference starting at Background, and then col. 3, lines 15-20.

In regard to particle size, Kwak teaches that problems in achieving the proper sizes are known because larger particle sizes are easily precipitated, thus causing the value of the commodity to be lowered, and being distasteful to consumers.

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It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify method of making a food product which provides vitamins and minerals to the consumer, including the provision of iron salt, as Misaki, to include coating of the iron salt with an emulsifying agent, as claimed, because Kwak teaches that such a limitation is known to overcome problems in the art and provide benefits such as improving solubility of iron and providing encapsulation so that more of the mineral is usable by the consumer.

The combined teaching of Misaki and Kwak fails to teach the specifically claimed particle size for the emulsified coated iron salt.

Nanbu, teaches that similar iron salts used for foods, having similar emulsified coated components such as polyglycerol fatty acid esters with oils, are effective for enriching food and feeds because they supplement individuals with deficiencies and maintain the good flavor of the food or feed; that they are produced to have particles sizes of less than 0.5 microns, as claimed; and that the absorption of mineral nutrients which typically have low absorptivity when taken intracorporeally will be improved. See the Background and starting at figure 3 and col. 4, lines 14+, including col. 5, lines 45+.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of making a food product which provides vitamins and minerals to the consumer, including the emulsified coated iron salt, as Misaki, to include coated iron salts in a particulate range of less than 0.5 microns, as provided by Nanbu, because the modified teaching of Misaki illustrates in Kwak that the

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trend in the art is to overcome the use of large particles sizes which create problems such as low solubility, bad taste, and a poor delivery of the desired dose to the consumer; and the because Nanbu teaches the use of emulsified coated iron salts having particles sizes of less than 0.5 microns allow for an improvement in the absorption of mineral nutrients.

Although, the modified teaching of Misaki in view of Kwak and Nanbu, teaches the use of emulsifying polyglycerol fatty acid esters as a coating agent for iron salt to make them more soluble so that a larger quantity of usable mineral is deliver to the consumer, the teaching fails to provide applicant's specifically claimed emulsifying agent, an enzymatically decomposed lecithin.

Tamaki teaches methods of making rice compositions that include iron salts, further include the emulsifiers, such as sucrose fatty acid esters, polyglycerol fatty acid esters, organic acid monoglycerides, lysolecithin, and diglycerol fatty acid esters, as effective additives.

The reference of WO/2008/140065 is provided as evidence that enzymatically decomposed lecithin is also referred to as lysolecithin, and that lysolecithin inherently provide improved hydrophilicity. See reference starting at para. 0060.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the of making a rice or barley grain product which provides vitamins and minerals to the consumer, including the emulsified coated iron salt, as Misaki, to include the specifically claimed enzymatically decomposed lecithin

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(i.e. lysolecithin), because one of skill would have a reasonable expectation of success in the teaching of Tamaki which illustrates that enzymatically decomposed lecithins are simple substitutions for the emulsifying polyglycerol fatty acid esters taught by the modified teaching of Tamaki, and further that they are suitable for the intended use of emulsifying rice compositions. Furthermore enzymatically decomposed lecithins (i.e. lysolecithin) inherently provides the benefit of improved hydrophilicity (i.e. water solubility), a property which is known to be beneficial in coating for rice and barley grain compositions.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention, because they work together to overcome the well known problems in the art by providing benefits to food compositions known to deliver vitamins and minerals to the consumer.

The prior art included each element claimed although not necessarily in a single reference, and one of ordinary skill in the art could have combined the elements as claimed by known methods of forming mineral and vitamin enriched grains, and in combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable. Further, a predictable use of prior art elements according to their established functions to achieve a predictable result is prima facie

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obvious. Further, *KSR Int'l Inc. v. Teleflex Inc.*, 127 S Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) teaches that "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton," and that "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."

In summary, the modified teaching above provides benefits for modifying the primary reference to include known components to the claims composition, and therefore the instant invention does not appear to be novel or exceed the inferences and creative steps that a person of ordinary skill in the art would employ, based on known teachings of the art.

Response to Arguments

On pages 5-8, it is asserted that the declaration by Sakaguchi (a co-inventor), of 12/08/2008, shows unexpected results and therefore the previous rejections have been overcome with evidence of record. Further, on page 8, it is noted that applicant asserts: "No mention is made with respect to the previously filed Rule 132 Declaration (as the instant rejection is new in view of a new combination of references). Accordingly, Applicants respectfully request reconsider of all arguments and evidence to date."

In response, the declaration has been considered, and in regard to the rejection of record, the experimental results offered in applicants' 37 C.F.R. 132 affidavit:

1) does not clearly provide specific data about the specific components or quantities of each and every composition used in the comparison, and therefore lacks

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comparative test data, because precisely what was done should be recited in the declaration: the actual steps carried out, the materials employed, and the results obtained should be spelled out. Nothing concerning the work relied upon should be left to conjecture or investigate;

2) does not provide a description of precisely what was tested: a) the invention as claimed; and b) the closest prior art, and therefore lacks technical description;

3) repeatedly discusses the results of washing the rice, however the claim is toward a product, not a method of washing, or the properties of the rice composition after it has been washed, and therefore is not commensurate with the scope of the claimed limitations;

4) does not appear to make a direct comparison between the claimed invention and the closest prior art, because the closest prior art has been relied on for each and every example; and

5) there is not a reasonable showing of statistical data that would conclude the experiment is factual as apposed to an occasional abnormality.

Further, even if a statistically accurate experiment was made, having a reasonable amount of statistical data, showing each of the components used including the quantities relied on, which showed unexpected results; the benefits provided for accomplishing the modifications to the primary reference can not be overlooked, because the references combined with the primary reference (Misaki) provide evidence that such combinations are known in the art to be effective and suitable for similar

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intended uses. Furthermore, whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the “objective evidence of onobviousness must be commensurate in scope with the claims which the evidence is offered to support.” In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range.

In summary, the modified teaching above provides benefits for modifying the primary reference to include known components to the claims composition, and therefore the instant invention does not appear to be novel or exceed the inferences and creative steps that a person of ordinary skill in the art would employ, based on known teachings of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. George whose telephone number is (571) 272-5955. The examiner can normally be reached on Mon. -Wed. between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia A George
Examiner
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